



Information Bulletin

No. 1-17 Urinalysis Testing

April 10, 2017

The Department of Drug and Alcohol Programs (DDAP) is issuing this Information Bulletin to clarify that substance abuse treatment programs, Single County Authorities (SCAs), and programs performing case management functions for the SCA are permitted to conduct urinalysis testing on individuals who are receiving assessment and/or treatment services. Facilities and other agencies must have written policies and procedures in place relative to urine testing.

DDAP licensed facilities must ensure that the laboratory performing the urinalysis is in compliance with applicable federal and state requirements. Specifically, facilities providing urinalysis must comply with the Clinical Laboratory Improvement Amendments (CLIA) of 1998 (42 USC 263a) and the associated federal regulations promulgated at 42 CFR 493. State requirements applicable to these facilities are the Pennsylvania Clinical Laboratory Act (35 P.S. §§ 2151—2165) and the associated state regulations promulgated at 28 Pa. Code § 5.1 - 5.104.

If the DDAP licensed facility intends to perform its own on-site drug-screening urinalysis, the facility must have a Clinical Laboratory Permit issued by the Pennsylvania Department of Health (DOH) and CLIA Certification issued by the U.S. Department of Health and Human Services, Center for Medicare and Medicaid Services. The facility must also use CLIA approved testing devices for on-site urinalysis.

The urinalysis results are confidential and should be kept in the individual's treatment/case management file as a part of his/her records. The restrictions on the release of the results of the urinalysis at 4 Pa. Code § 255.5 continue to apply.

This Information Bulletin is not intended to address regulations and/or policies relative to Narcotic Treatment Programs.

Questions from treatment providers concerning this Information Bulletin can be addressed to the Division of Drug and Alcohol Program Licensure at 717-783-8675.

Questions from SCAs or their case management contracted providers concerning this Information Bulletin can be addressed to the Treatment Division at 717-783-8200.

Information about Clinical Laboratory Permits and/or CLIA Certification can be found at <http://www.health.pa.gov/labs> or by contacting the DOH, Bureau of Laboratories at 610-280-3464.

JS/TJ/TWM/TM/JS/JDG:dem

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